DQS Medizinprodukte GmbH
August-Schanz-Strasse 21
D-60433 Frankfurt am Main
Germany

Attn: Marc Goedecke
Produktmanager MDSAP
Zertifizierungsstelle

RE: Re-recognition as Auditing Organization under the Medical Device Single Audit Program (MDSAP)

Dear Mr Goedecke,

Considering:

1. The Statement of Cooperation among the United States Food and Drug Administration (US FDA), the Australian Therapeutic Goods Administration (TGA), the Brazilian Health Surveillance Agency (ANVISA), and the Canadian Health Products and Food Branch (Health-Canada) regarding cooperation in the Medical Device Single Audit Program (MDSAP), signed in Manaus, Brazil on November 27th, 2012;

2. The MDSAP Functional Statement (Document #: MDSAP P0001) among US FDA, TGA, ANVISA, Health-Canada, and Japan's Ministry of Health, Labour and Welfare and the Japanese Pharmaceuticals and Medical Devices Agency (MHLW/PMDA);

3. The assessments of the compliance of DQS Medizinprodukte GmbH to the requirements set out in the IMDRF MDSAP WG documents N3[1] and N4[2], performed between 26th April 2017 and 16th May 2022, as listed in schedule 1;

4. The recommendation from the assessment team leaders; and

[1] IMDRF MDSAP WG N3 - Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition

[2] IMDRF MDSAP WG N4 - Competence and Training Requirements for Auditing Organizations

5. The review of the assessment file by the Technical Review and Recommendation Committee and the endorsement of their decision by the MDSAP Regulatory Authority Council.

TGA, ANVISA, Health-Canada, MHLW/PMDA and the US FDA, as listed on the Schedule 2, decided to continue the recognition of DQS Medizinprodukte GmbH as an auditing organization under the MDSAP.

This decision by the signatories of the Statement of Cooperation and the MDSAP Functional Statement, on 27 November, 2022, takes effect the same day.

The recognition is conditional upon continued compliance with MDSAP requirements, and the additional conditions documented in the Schedule 3 (if any), and is valid for a period of four (4) years starting on the date of decision and expiring on 27 November, 2026.

Kenichi Ishibashi

Kenichi Ishibashi
Chair of the Regulatory Authority Council
Date: 2023/03/02

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